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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,028	10/02/2005	Nicolas De Roux	CABH.P0006	6884

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STATTLER, JOHANSEN, AND ADELI LLP
1875 CENTURY PARK EAST SUITE 1360
LOS ANGELES, CA 90067

EXAMINER	
ALLEN, MARIANNE P	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 11/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/552,028	DE ROUX ET AL.	
	Examiner	Art Unit	
	Marianne P. Allen	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 29-39 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 29-39 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-28 have been cancelled. Claims 29-39 have been newly introduced.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 29-39 are not originally filed claims. They were added in the preliminary amendment filed 10/2/05; however, no basis in the specification was provided for these claims and none is apparent.

Claims 29-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an enablement rejection.

The claims require Kiss-1 peptide, fragment 45-54 of Kiss-1, Kiss-1 peptide fragments, kisspeptins, or salts thereof. The specification does not provide the sequence of Kiss-1 or any of

the fragments. The specification does not provide a limiting definition of those proteins or fragments that would meet the limitation of "Kiss-1" or "kisspeptins." The specification refers to WO-A-2003003983, EP-A-1126028, and US-A-2002-106766 on page 8 as disclosing peptides included. First of all, it is noted that this does not define the metes and bounds of all peptides intended to be embraced. Furthermore, the specification does not express a clear intent that any or all of these documents are intended to be incorporated by reference. See MPEP 608.01(p). Secondly, even if a clear intent had been present this would be an improper incorporation by reference of essential material for WO-A-2003003983 and EP-A-1126028. The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Finally, it does not appear that any of these documents clearly disclose Kiss-1 or kisspeptins but rather appear to discuss its receptor.

With the exception of fragment 45-54 of Kiss-1 as discussed on page 17, the specification does not disclose any activity for these proteins in combination with GnRH. The specification does not disclose any other fragments of Kiss-1 that would have activity, particularly in combination with GnRH.

Figure 5 and page 17 disclose using the combination of fragment 45-54 of Kiss-1 and GnRH in an in vitro perifusion assay of rat pituitary tissue. The 45-54 fragment of Kiss-1 at 10^{-8} M and GnRH at 10^{-6} M shows modulation of the GnRH effect on LH synthesis. This combination extends the effect of GnRH on LH stimulation by the pituitary. However, other concentrations or ratios of Kiss-1 or GnRH are not tested and it cannot be predicted that other Kiss-1 or kisspeptin peptides or other amounts of these peptides with other amounts of GnRH would have any activity.

The specification does not disclose that this perifusion model of rat pituitary is an art accepted model of any disease state or medical condition such that these results could be extrapolated to an in vivo method of treatment for any disease state or medical condition. For example, stimulation of ovulation (see claim 34) and general treatment of gonadotropin related reproductive disorders (see claim 32) involve complex regulatory feedback loops that extend well beyond the pituitary. Note also that the specification discloses that loss of GPR54 function leads to impuberism or hypogonadotropic hypogonadism. If the receptor for Kiss-1 is not functional, the specification does not make clear how additional Kiss-1 will provide any compensating effect.

For these reasons, the specification does not enable producing the claimed compositions nor how to use the claimed compositions.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32-35 and 37-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 32-35 are directed to the compositions of claims 29-31 with the only additional limitation being an intended use. The recitation in claim 32 "for its therapeutic use in the treatment of a gonadotropin related reproductive disorder" does not limit further limit the composition itself. It adds no additional limitations to the GnRH or Kiss-1 peptide or fragments

as recited in claims 29-31. As such, these claims are confusing in failing to further limit the subject matter.

Similarly, the intended use in claim 37 does not further define the Kiss-1 peptide, Kiss-1 peptdie fragments, kisspeptins, or salt thereof of claim 36. The claim is further confusing in reciting "the use according to claim 36." Claim 36 is directed to peptides and not a use.

Claims 38-39 are confusing in reciting "for the use according to claims 36 or 37" and "for the use according to any one of the claims 36-38." These claims are directed to peptides and not uses. Particularly with respect to claim 39, none of claim 36-38 require GnRH. As such, the recitation of ranges in the claim is confusing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 36-39 are rejected under 35 U.S.C. 102(e) as being anticipated by Suenaga et al. (U.S. Patent No. 6,838,259).

Claims 36, 37, and 39 are directed to Kiss-1 peptide, Kiss-1 peptide fragments, kisspeptins, or salts thereof. Claim 38 is further limited to fragment 45-54 of Kiss-1. The

intended use language of these claims is given no patentable weight in a product claim and the only positive recitation is the peptides.

Suenaga et al. discloses KiSS-1 peptides, particularly the 45-54 amino acid fragment. See at least abstract, SEQ ID NO: 1, and claims.

Claims 29 and 31-35 are rejected under 35 U.S.C. 102(a) as being anticipated by Seminara et al. (*New England Journal of Medicine*, 23 October 2003).

Applicant claims benefit to EPO 0329083.1 filed 4/2/2003; however, the presently claimed Kiss-1 peptides and compositions of Kiss-1 peptides and GnRH are not disclosed in this document. The effective filing date for these claims is the filing date of PCT/EP04/004132, namely 4/2/2004. As such, Seminara et al. is valid prior art against the instant application.

Seminara et al. discloses injecting GnRH into mice and examining pituitary specimens. See page 1617. Seminara et al. disclose that a natural ligand for GPR54 is kisspeptin-1. See page 1616. Mice were also injected with a dose of a Kisspeptin1 fragment. See Figure 3B and page 1620. See also Figure 6E for measurements of GnRH levels in hypothalamic extracts.

The claims do not indicate that the composition is isolated or purified or that any components are isolated or purified. As such, the mice disclosed by Seminara et al. would have GnRH and the naturally occurring ligand kisspeptin-1 present, thereby meeting the limitations of the claimed composition. Absent evidence to the contrary, the molar concentrations required by claim 31 would appear to be inherently present in the mice given the wide range embraced by the claim.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Friday, 5:30 am - 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marianne P. Allen
Primary Examiner
Art Unit 1647

10/31/06

mpa